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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,323	12/30/2003	Stefan M. Pulst	3350.1000-005	4927

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/750,323

Applicant(s)

PULST, STEFAN M.

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed October 17, 2006.
2. Currently, claims 1-41 are pending. Claims 1-26 are withdrawn from consideration. Claims 27-29, 31-41 have been canceled.
3. Claim 30 is examined on the merits.
4. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
5. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Priority

6. The instant application claims priority to parent application , 09/083, 268 filed May 22, 1998 and 08/727,084 filed 10/8/96 and provisional applications filed 5/8/96 and 7/19/96.

Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application:

In the amended claims 30, reference to "nucleotides 303 to 657 of SEQ ID NO: 2" and "723 to 890 of SEQ ID NO: 2" are included. The amendment proposes that the

new claim language is supported on pages 20, 32, 33, 34, Example 3 and Figure 6a. The passage from page 20 is not directed to amplification primers and their binding regions. The passage on page 32 is not directed to primers. The passage on page 33 states using "primers that amplify at least a nucleic acid fragment of SEQ ID NO: 2 containing nucleotides 658-723 of SEQ ID NO: 2". This recitation within the specification, while provide support for amplifying using primers which would amplify the CAG repeat region, does not provide basis for the specific position of 303-657 and 723-890 of SEQ ID NO: 2. On page 34, lines 15-26, the specification teaches diagnostic nucleic acids are derived from SEQ ID NO: 2 (Figure 6), preferably derived from nucleotides 163-657 and nucleotides 724-4098, with primes SCA2-A and SCA2-B being especially preferred. While this passage supports primers which are upstream and downstream of the CAG repeat region, this does not provide support for the narrow genus of primer binding regions which are instantly claimed. At the time the invention was made, based upon the specification, the applicant's do not appear to have contemplated that the narrow regions of 303-657 and 723-890 of SEQ ID NO: 2. The concept of "nucleotides 303 to 657 of SEQ ID NO: 2" and "723 to 890 of SEQ D NO: 2". does not appear to be part of the originally filed invention. Therefore, recitation "nucleotides 303 to 657 of SEQ ID NO: 2" and "723 to 890 of SEQ ID NO: 2" constitutes new matter.

With respect to Claim 36, the amendments provides that a probe is used to measure the number of CAG repeats, wherein the probe has a sequence greater than 22 CAG repeats. The amendment teaches that support for the claim may be found on

pates 20, 21, 22, 33 and Example 3 and 4. The recitation on page 20 does not provide any support for a (CAG)₂₂ probe. Page 20 does discuss probes, but the text does not provide any indication that the probe is a CAG repeat probe or that the probe contains more than 22 repeats. Pages 21-23 fail to discuss CAG probes. Example 3 teaches hybridizing PCR products with (CAG)₁₀ probes (page 43, lines 33-34). The specification fails to provide any contemplation of a (CAG)₂₂ probe for determining the number of CAG repeats. The concept of "a probe having a sequence greater than 22 CAG repeats" does not appear to be part of the originally filed invention. Therefore, recitation "a probe having a sequence greater than 22 CAG repeats" constitutes new matter.

Therefore, the instant claims are afforded the instant priority date of **December 30, 2003** because they are not supported by the earlier applications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 30 is rejected under 35 U.S.C. 102(b) and 102(g) as being anticipated by Tsuji et al (US Pat. 6,251,589, June 26, 2001).

Tsuji teaches a method for diagnosing spinocerebellar ataxia type 2 in a human nucleic acid sample comprising the steps of: amplifying said nucleic acid sample with a

first primer and a second primer by polymerase chain reaction wherein said first primer hybridizes to a region of SEQ ID NO: 1 and said second primer hybridizes to a region of SEQ ID NO: 3; obtaining an amplification product of said nucleic acid sample by said polymerase chain reaction; and measuring a number of CAG repeats in said amplification product, wherein a number of 35 or more CAG repeats in said nucleic acid sample is indicative of said spinocerebellar ataxia type 2 and a number of 15-24 CAG repeats in said nucleic acid sample would be negative for SCA2. Tsuji teaches specific techniques of measuring and analyzing the CAG repeats of the SCA2 gene, namely gel electrophoresis, sequencing, and using hybridization probes (Claims 4-6 of 6,251,589).

Furthermore as provided in the working Example 2 of Tsuji, Tsuji teaches that in all of the normal genes, the numbers of the CAG repeat units were not more than 24, while in all of the SCA2 genes, they were not less than 35 (col. 6, lines 45-50).

Claim 30 recites that primers within 303-657 and 723-890 of SEQ ID NO: 2 of the instant application are used. Tsuji specifically teaches using primers from within SEQ ID NO: 1 which is nucleotides 303-657 of SEQ ID NO: 2 of the instant application and 723-890 of SEQ ID NO: 2 of the instant application is SEQ ID NO: 3 of Tsuji. Moreover, the specific primers of SEQ ID NO: 19 and 20 of Tsuji are located within these specifically enumerated region.

Furthermore, the claim has been amended to require that the probe has greater than 22 CAG repeats. Tsuji specifically teaches using a probe having SEQ ID NO: 17. SEQ ID NO: 17 is a probe of 55 CAG repeats.

Thus, Tsuji teaches every limitation of the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 27-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of U.S. Patent No. 6,673,535.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentable distinct from each other because Claims 27-41 of the instant application is generic to all that is recited in Claims 1-4 of U.S. Patent No. 6,673,535. That is, Claims 1-4 of U.S. Patent No. 6,673,535, fall entirely within the scope of Claim 27-41, or in other words, Claim 27-41 are anticipated by Claims 1-4 of U.S. Patent No. 6,673,535. Here, claim Claims 1-4 of U.S. Patent No. 6,673,535 recites a method for determining whether a human is negative for SCA2 by amplifying using two primers wherein 22 CAG repeats would be negative for SCA2. It is noted 22 CAG repeats is within the range of "normal" and 15-24. The claims are also drawn to detecting SEQ ID NO: 1. Each of the instant claims are within the scope of the patented claims. It is noted that SEQ ID NO: 1 is the genomic DNA for SCA2 and SEQ ID NO: 2 is the cDNA for SCA2. However each of the recited sequences are within the coding cDNA. Thus, Claims 1-4 of U.S. Patent No. 6,673,535 teaches every limitation of the instant claims.

Response to Arguments

The response notes the rejection and will file a terminal disclaimer upon indication that the only remaining rejections are Double patenting rejections. Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

9. No claims allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

A handwritten signature in black ink, reading "J. Goldberg". The signature is fluid and cursive, with the first letter "J" being large and prominent.

Jeanine Goldberg

Primary Examiner

November 29, 2006